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**UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK**

MERZ NORTH AMERICA, INC.,)	Civil Action No.: 1:19-cv-4520
)	
Plaintiffs,)	
)	
v.)	
)	
ANGIODYNAMICS, INC.,)	COMPLAINT
)	
Defendant.)	

Plaintiff Merz North America, Inc. (“Merz”) hereby files this Complaint against Defendant AngioDynamics, Inc. (“AngioDynamics”) (Merz and AngioDynamics are referred to hereinafter, collectively, as the “Parties”), and alleges as follows:

NATURE OF THE ACTION

1. This is an action for damages arising from AngioDynamics’ repeated and uncured material breaches of a Distribution Agreement dated March 1, 2016 between the Parties (the “Agreement”), pursuant to which AngioDynamics agreed to become the exclusive sub-distributor for certain formulations of the injectable drug product Asclera® (the “Products”) in the Designated Market in the Territory (as those terms are defined in the Agreement). A redacted copy of the Agreement is attached hereto as Exhibit A.

2. As set forth in Section 3.1 and Exhibit C of the Agreement, AngioDynamics agreed, among other things, to purchase a minimum number of Units of the Product in a

Calendar Year during the Term of the Agreement. The Agreement defines this minimum amount as the “Annual Minimum.”

3. Section 3.1 of the Agreement also required AngloDynamics to make a “True-Up Purchase” within sixty (60) days following the end of a Calendar Year if it did not purchase the applicable Annual Minimum during any Calendar Year as set forth in Exhibit C of the Agreement.

4. The Agreement also provided for AngloDynamics to pay an “Annual Fee” in annual installments, which are currently due and payable pursuant to Section 7.7.

5. AngloDynamics has materially breached the Agreement by failing to purchase the required Annual Minimum for Calendar Year 2018, by failing to make the required True-Up Purchase (as defined in the Agreement) for Calendar Year 2018, by failing to pay the Annual Fee, and by failing to perform numerous other obligations as specified in the Parties’ Agreement and alleged further herein.

6. As a result of AngloDynamics’ material uncured breaches of the Agreement, and after numerous prior notices and demands for performance as further alleged herein, Merz gave AngloDynamics notice on April 5, 2019 of Merz’s termination of the Agreement pursuant to Sections 7.2, 7.4, and 7.7 of the Agreement (“Termination Notice”). A copy of the Termination Notice is attached hereto as Exhibit B.

7. Pursuant to the Termination Notice and Section 7.7 of the Agreement, all of AngloDynamics’ rights and licenses with respect to the Product have been terminated, AngloDynamics is required immediately to cease marketing and selling the Products, and all payments due to Merz under Section 5 of the Agreement are due and payable.

8. Merz brings this action for compensatory damages to recover the substantial losses it has incurred as a result of AngloDynamics' material breaches of the Agreement.

PARTIES

9. Merz is a North Carolina corporation with its principal place of business at 6501 Six Forks Road, Raleigh, North Carolina.

10. Upon information and belief, AngloDynamics is Delaware corporation with its principal place of business at 14 Plaza Drive, Latham, New York.

JURISDICTION AND VENUE

11. This Court has original subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1332(a). Plaintiff Merz is a citizen of North Carolina. Defendant AngloDynamics is a citizen of Delaware and New York. The amount in controversy exceeds \$75,000, exclusive of interest and costs.

12. This Court has personal jurisdiction over the Parties because the Parties agreed, pursuant to Section 12.2 of the Agreement, that:

Each Party hereby submits itself for the purpose of this Agreement and any controversy arising hereunder to the exclusive jurisdiction of the United States District Court for the Southern District of New York (or if that court is unable to exercise jurisdiction for any reason, the Parties hereby consent to the exclusive jurisdiction of the New York State Supreme Court, New York County, United States), and any course of appeal therefrom, and waives any objection on the grounds of lack of jurisdiction (including, without limitation, venue) to the exercise of such jurisdiction over it by any such courts.

13. Venue in this Court is proper, additionally, pursuant to 28 U.S.C. § 1391(b)(2) because a substantial part of the events giving rise to the claims occurred in New York, and because the Parties agreed that the Courts of New York are the "exclusive" venue for claims arising out of or in connection with the Agreement.

FACTS

Background of the Agreement

14. Merz is a specialty healthcare company dedicated to the development and marketing of innovative quality products for physicians and patients across the United States.

15. AngioDynamics is a NASDAQ-listed public company headquartered in New York that operates facilities in the United States, Europe, Asia, and Latin America. AngioDynamics touts itself as a “leading provider of innovative medical devices used by interventional radiologists, interventional cardiologists, surgeons, and other physicians for the minimally-invasive diagnosis and treatment of cancer and peripheral vascular disease.”

16. AngioDynamics sells products owned or licensed by it in the United States, including the Products that are the subject of the Agreement, through a direct sales force employed and managed by AngioDynamics.

17. Chemische Fabrik Kreussler & Co. GmbH (“Kreussler”) is a German company and is the owner of a U.S. New Drug Application for the pharmaceutical product known as Asclera®, NDA No. 021201. Asclera® is an intravenous drug product used for the treatment of varicose veins.

18. Kreussler and Merz are parties to a Licensing and Distribution Agreement dated May 11, 2007, as amended, pursuant to which, among other things, Kreussler has granted to Merz the right to distribute Asclera® in the United States (the “Kreussler Agreement”).

19. Following the execution of the Kreussler Agreement, Merz and AngioDynamics entered into the Agreement, with an Effective Date of March 1, 2016, which required Merz to supply AngioDynamics with Units of the Product for sale in the Territory specified in the Agreement.

20. AngioDynamics expressly acknowledged that Merz had the right to distribute Asclera®, and to grant sub-distribution rights, subject to the terms of the Kreussler Agreement and as set forth in Section 3.3 of the Agreement.

21. Pursuant and subject to the terms of the Agreement, including timely payment of all amounts payable under the Agreement, Merz appointed AngioDynamics as Merz's exclusive distributor for the Products to the Designated Market in the Territory during the Term (as such terms are defined in the Agreement). Merz also granted AngioDynamics an exclusive, non-transferable right and license (without the right to sublicense or appoint sub-distributors) to market, sell and distribute the Products to the Designated Market in the Territory during the Term.

AngioDynamics' Obligations Under the Agreement

22. In return for the appointment and license described immediately above, AngioDynamics agreed to purchase the Products exclusively from Merz. In addition, pursuant to Section 3.1 of the Agreement, AngioDynamics committed to purchase a minimum amount of Products from Merz on an annual basis during the Term of the Agreement (as defined above, the "Annual Minimum.")

23. The Annual Minimum was a foundational requirement of the Agreement, and is part of the essential consideration on which the Agreement was based. The purpose of the Annual Minimum is to ensure that AngioDynamics purchases sufficient quantities of Products each Calendar Year during the Term of the Agreement to allow Merz to satisfy its own purchase obligations to Kreussler under the terms of the Kreussler Agreement, while providing Merz a reasonable profit over and above its costs for such Products.

24. Pursuant to Section 3.1 of the Agreement, if AngioDynamics does not purchase the applicable Annual Minimum during any Calendar Year, within sixty (60) days following the

end of such Calendar Year, “AngioDynamics shall purchase and take delivery of sufficient quantities of the Product to meet the Annual Minimum for the immediately prior Calendar Year (the “True-Up Purchase”).”

25. The Annual Minimum provides a baseline for measuring AngioDynamics’ performance under the Agreement, with the expectation that AngioDynamics would, over time, sell more Products on an annual basis than the proscribed Annual Minimum. To that end, AngioDynamics agreed, pursuant to Section 3.2 of the Agreement, to use commercially reasonable efforts to continuously increase the sale of the Products in the Designated Market in the Territory during the Term so long as Merz supplied Products to AngioDynamics in accordance with the Agreement.

26. In addition to the core obligations described above, AngioDynamics agreed to numerous other material obligations under the Agreement, including without limitation, the obligations to:

- a. no later than the tenth (10th) day of each month, provide Merz with a forecast of Products that AngioDynamics anticipates ordering from Merz for each of the coming twelve (12) months (as defined in the Agreement, the “Rolling Forecast”), pursuant to Section 4.1 of the Agreement;
- b. beginning in the 2017 Calendar Year, submit binding monthly purchase orders to Merz with each Rolling Forecast, as further described in Section 4.2 of the Agreement;
- c. pay the “Annual Fee” pursuant to Section 5.3 of the Agreement, which is now due and payable in accordance with Section 7.7 of the Agreement; and
- d. reimburse Merz for 75% of fees for Products incurred by Merz during the remaining Term under the Prescription Drug User Fee Act (“PDUFA Fees”), pursuant to Section 5.6 of the Agreement.
- e. pay a “late charge” of one-half percent (0.5%) per month, or the maximum rate permitted by applicable law, whichever is lower, in the event that AngioDynamics fails to make any payment to Merz due under the Agreement.

AngioDynamics' Material Breaches of the Agreement

27. AngioDynamics failed to timely satisfy its annual purchase commitments for the 2018 Calendar Year and failed to increase the sale of the Products as required by the Agreement. By the end of 2018, sales of the Products had declined compared to prior years, and AngioDynamics had purchased only a small fraction (less than 3%) of the quantities of Products required to satisfy the 2018 Annual Minimum. In addition, prior to Merz's termination of the Agreement, discussed *infra*, AngioDynamics failed to purchase from Merz quantities of the Product, as obligated, for the first quarter of Calendar Year 2019.

28. AngioDynamics failed to satisfy its obligation to make a "True-Up" payment within sixty (60) days after the end of Calendar Year 2018.

29. Upon failing to purchase the Annual Minimum in Calendar Year 2018 and failing to make the "True-Up" payment, AngioDynamics was required under Section 5.10 to pay a late charge of one-half percent (0.5%) per month which, to date, has not been paid.

30. In addition, AngioDynamics failed to fulfill its forecast obligations for 2018 under Section 4.1 of the Agreement and failed to submit monthly binding purchase orders with its forecasts, as required by Section 4.2 of the Agreement.

31. AngioDynamics also failed to pay the prorated portion of the PDUFA fee for the first quarter of Calendar Year 2019 pursuant to Section 5.6 of the Agreement.

**AngioDynamics' Failure to Cure its Material Breaches and
Merz's Termination of the Agreement**

32. By letter dated January 2, 2019, Merz gave AngioDynamics notice that it had materially breached the Agreement by failing to fulfill its forecast obligations under Section 4.1, and by failing to fulfill its purchase order obligations under Section 4.2 of the Agreement. Merz further notified AngioDynamics that it had failed to purchase the Annual Minimum for 2018 and

that, if AngloDynamics failed to make the “True-Up” payment required by Section 3.1, then Merz would have the right to terminate the Agreement pursuant to Section 7.4.

33. AngloDynamics refused to cure its material breaches of the Agreement or provide adequate assurances of performance.

34. Over the next two (2) months, Merz and AngloDynamics exchanged letters representing each party’s respective positions with regard to AngloDynamics’ material breaches.

35. In these letters, AngloDynamics essentially repudiated the Agreement with Merz and failed to provide adequate assurances of performance, despite Merz’s repeated requests for such assurances.

36. By letter dated February 23, 2019, and without waiver of its position that AngloDynamics had repudiated the Agreement, Merz offered to postpone further immediate action to enforce its rights, conditioned upon AngloDynamics’ agreement to meet with Merz and discuss in good faith the terms for continued performance or termination of the Agreement. Executives of the Parties met thereafter to discuss resolution of their dispute, but were unable to reach agreement.

37. AngloDynamics failed to make the True-Up Purchases for the 2018 Calendar Year when due. By letter dated March 6, 2019, and again without waiver of its position that AngloDynamics had repudiated the Agreement, Merz notified AngloDynamics of its failure to make a timely True-Up Purchase, and of Merz’s right to terminate pursuant to Sections 7.2 and 7.4 of the Agreement if AngloDynamics failed to timely cure its breaches.

38. AngloDynamics failed to cure any of its continuing and multiple material breaches of the Agreement, including its failure to make the 2018 True-Up Purchase. As previously alleged herein, based on AngloDynamics’ continuing and uncured material breaches

of the Agreement, Merz gave its Termination Notice to AngloDynamics by letter hand-delivered to AngloDynamics on April 5, 2019 (*See Exhibit B hereto*).

39. Upon the termination of the Agreement, and pursuant to Section 7.7 of the Agreement, AngloDynamics was required to make all payments due to Merz under Section 5 of the Agreement, including the Annual Fee contemplated in Section 5.3.

40. From January 1, 2019 until Merz terminated the Agreement on April 5, 2019, AngloDynamics failed to order additional quantities of the Product, as obligated.

CLAIM FOR RELIEF

(Breach of Contract)

41. The allegations of paragraphs 1 through 40 of the Complaint are realleged and incorporated herein by reference as fully as if set forth individually.

42. The Agreement is a valid and binding contract between the Parties enforceable in accordance with its terms in New York under New York law.

43. Prior to termination of the Agreement, Merz had performed all of its obligations under the Agreement and had fully complied with the terms thereof.

44. AngloDynamics has materially breached numerous contractual covenants, obligations, and agreements under the Agreement, and has failed to cure such breaches after notice within the time allowed by the Agreement, including, without limitation, by failing to:

- a. purchase the Annual Minimum for Calendar Year 2018, as required by Section 3.1 of the Agreement;
- b. purchase a pro-rated portion of the Annual Minimum for the first quarter of Calendar Year 2019 prior to Merz's election to terminate the Agreement due to AngloDynamics' uncured material breaches;
- c. make the True-Up Purchase for Calendar Year 2018, as required by Section 3.1 of the Agreement;
- d. pay the PDUFA fees pursuant to Section 5.6 of the Agreement;

- e. provide Merz with a Rolling Forecast of Products for the 2018 Calendar Year in accordance with Section 4.1 of the Agreement;
- f. submit binding monthly purchase orders with each Rolling Forecast in accordance with Section 4.2 of the Agreement;
- g. pay the remaining aggregate balance of the Annual Fee in accordance with Sections 5.3 and 7.7 of the Agreement; and
- h. pay the applicable late charges to Merz for overdue amounts pursuant to Section 5.10 of the Agreement.

45. As a direct and proximate cause of AngloDynamics' breaches of the Agreement as alleged herein, Merz has sustained injury and is entitled to recover compensatory damages from AngloDynamics in an amount to be proven at trial.

46. Prior to the filing of this lawsuit, the Parties attempted in good faith to settle this dispute in accordance with Section 12.9 of the Agreement. More than twenty (20) days have passed since the first request for dispute resolution under Section 12.9, and neither party has requested that the dispute be submitted to non-binding mediation.

PRAYER FOR RELIEF

WHEREFORE, Merz respectfully requests relief against AngloDynamics as follows:

- 1. That Merz be awarded judgment in its favor against AngloDynamics on all claims for relief set forth herein;
- 2. That Merz recover compensatory damages against AngloDynamics in an amount to be proven at trial, including but not limited to:
 - a. the unpaid Annual Minimum for Calendar Year 2018 in the estimated amount of \$7,004,700.00, pursuant to Section 3.1 of the Agreement;
 - b. the unpaid Annual Minimum for Calendar Year 2019, prorated through the date of Termination in an amount to be determined at trial;
 - c. Merz's expected profit margin for the last three quarters of 2019 through the end of 2022, which is in excess of \$14,000,000.00, when the Term of the Agreement expired;

- d. the PDUFA fees for the first quarter of Calendar Year 2019, which is in excess of \$100,000.00, pursuant to Section 5.6 of the Agreement;
- e. the remaining aggregate balance of the Annual Fee pursuant to Sections 5.3 and 7.7 of the Agreement, which is \$500,000;
- f. late charges on the unpaid amounts set forth above as determined in accordance with Section 5.10 of the Agreement; and
- g. such further damages, including direct damages incurred for the remaining Term of the Agreement, amounts that Merz is required to expend pursuant to its agreement with Kreussler as a direct result of AngloDynamics' breach, and other losses as may be proven at the trial of this action.

3. That the costs of this action be taxed against AngloDynamics and that Merz be awarded its attorneys' fees, as may be allowed by law;

4. For such other and further relief as the Court may determine is just and proper.

CONNELL FOLEY, LLP

Dated: May 16, 2019

By: /s/ Patrick J. Hughes

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